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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,034	09/22/2003	Griscom Bettie III	15783	4995
7590 Scully, Scott, Murphy & Presser 400 Garden City Plaza Garden City, NY 11530			EXAMINER CARR, DEBORAH D	
			ART UNIT 1621	PAPER NUMBER
			MAIL DATE 02/12/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/670,034	Applicant(s) BETTLE ET AL.	
	Examiner DEBORAH D. CARR	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 and 63-70,88 is/are pending in the application.
- 4a) Of the above claim(s) 11-34,37-61,63-67,69,70 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 87 is/are allowed.
- 6) ☒ Claim(s) 1,2,10,35,36,68,74,75 and 88 is/are rejected.
- 7) ☒ Claim(s) 3-9 and 78-84 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see pages 18-28, filed 4 October 2007, with respect to the rejection(s) of claim(s) 1-2, 68, 71-73, 86-87 under 35 USC§102(b) in view of Change et al., JP'203, JP'352, US'408, US'273, US'783 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. The rejections made under 35 USC§102(b) in view of US'059 and 35USC§112 2nd paragraph is being maintained. However, upon further consideration, JP'352 is being reapplied in view of 35 USC§102.
2. Claims 11-34, 37-61, 64-67, 69-70 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant having timely traversed the restriction (election) requirement in the replies filed 11 September 2006 & 4 October 2007. The requirement is still deemed proper and remains FINAL.
3. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

(Old) Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 1-2, 35, 68, 88 rejected under 35 U.S.C. 102(b) as being clearly anticipated by Fukumaru et al. (US Pat. 3,995,059).

Applicant argues the amendment of independent claims 1, 35 and 88 removing "lower alkyl" from the definition of R₅, removes this anticipation rejection. However, it should be noted that US'059 teaches compounds that anticipate these claims as newly amended.

Listed in columns 159, 161, and 169 are amines used to produce the fatty amide compounds via amidation of a fatty acid chloride and amine. Clearly once reacted, the amide will contain compounds wherein the nitrogen is substituted with 2 aryl moieties or 2 lower aryl moieties. (See examples numbered 1275, 1287, 1344.)

(Old) Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 10 & 85-86 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 & 85-86 recites the limitation "benzethonium linoleamide and benzethonium stearamide" in line 2. There is insufficient antecedent basis for this limitation in the claim. Page 3, section [0008] list the quaternary ammonium salts as a completely different invention and separate from the pharmaceutically acceptable salts of the instant compounds.

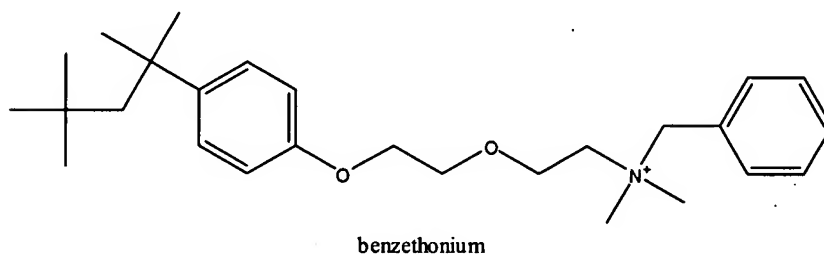
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Applicant has supplied the structure of the compound in question on pages 31-32. This compound contradicts applicants' definition of quaternary ammonium compounds given in section [0030]. It is clearly stated in section [0030]:

[0030]

The quaternary ammonium salts used in the present invention include **four groups around the central nitrogen atom**. They may include combinations of short chain alkyl groups, containing 1-4 carbon atoms, fatty groups, aryl, and aryl lower alkyl group.

The benzethonium moiety is as follows:



The structure clearly shows the nitrogen atom has a charge of +1 which should be retained in benzethonium linoleamide and benzethonium stearamide. Therefore these claims do not fit the compounds of claim 1, lacking antecedent basis.

The following rejections are deemed proper.

(New) Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-2 rejected under 35 U.S.C. 102(b) as being clearly anticipated by JP/01-201325.

JP'325 teaches fatty acid containing tertiary amides that read in the instant compounds. The actual compounds reading on the instant invention are shown in Chem. Abstr. of the patent.

10. Claims 1-2, 35-36, 68 rejected under 35 U.S.C. 102(b) as being clearly anticipated by GB-1,110,612.

GB'612 teaches fatty acid containing tertiary amides that read in the instant compounds (see pages 4, 6, 8). The actual compounds reading on the instant invention are shown in Chem. Abstr. of the patent.

11. Claims 74-75 rejected under 35 U.S.C. 102(b) as being clearly anticipated by Shroot et al. (US Pat. 4,877,789).

Claim(s) 74-75 is/are product-by-process claims. M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps."

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even

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though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)

The use of 35 U.S.C. §§ 102 and 103 rejections for product-by-process claims has been approved by the courts. “[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith.” *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

US'789 teaches fatty acid containing tertiary amides hydrates that read in the instant compounds, compositions, and their inclusion in mixtures, see cols. 1-2 & 7. Also taught in col. 2, lines 50-54 are pharmaceutically and cosmetically acceptable salts such as the salts of inorganic acid, which encompasses hydrates, and in amounts that read on the instant transdermal effective amounts (col. 8, lines 26-38).

Allowable Subject Matter

12. Claims 3-9, 76-87 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBORAH D. CARR whose telephone number is (571)272-0637. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-

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9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah D Carr/
Primary Examiner
Art Unit 1621

Ddc